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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02/04/2002
C(2002) 1373

NOT FOR PUBLICATION

COMMISSION DECISION

of 02/04/2002

**amending Decision C(2001)286 on the marketing authorization for
the medicinal product for human use**

"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

(Text with EEA relevance)

ONLY THE GERMAN TEXT IS AUTHENTIC.

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of 02/04/2002

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"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products¹, as amended by Commission Regulation (EC) No 649/98²,

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93³, as amended by Commission Regulation (EC) No 1069/98⁴, and in particular Article 8(3) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

- (1) The medicinal product "Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase" entered in the Community register of medicinal products under Nos EU/1/00/168/001-003 authorised by Commission Decision C(2001)286 of 23 February 2001, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.
- (2) Boehringer Ingelheim International GmbH submitted an application on 11 December 2001 pursuant to Article 6(1) set out in Regulation (EC) No 542/95.
- (3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 13 December 2001 by the Committee for Proprietary Medicinal Products,

¹ OJ No L 214, 24. 8. 1993, p. 1.

² OJ L 88, 24.3.1998, p. 7.

³ OJ No L 55, 11.3.1995, p. 15

⁴ OJ L 153, 27.5.1998, p. 11

- (4) Decision C(2001)286 should therefore be amended accordingly.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2001)286 is amended as follows:

1. Annex I is replaced by Annex I to this Decision;
2. Annex III A is replaced by Annex II to this Decision.

Article 2

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 02/04/2002

For the Commission
Erkki LIIKANEN
Member of the Commission